

COMMONWEALTH OF VIRGINIA
Department of Health Professions
Richmond, Virginia

DATE: _____
TIME: _____
MILEAGE: _____
INSPECTION HOURS: _____

Medical Practitioner Inspection Report

Practitioner's Name: _____ License No.: _____

Address: _____

Other Licensees: _____ Lic. No.: _____ Exp. Date: _____

_____ Lic. No.: _____ Exp. Date: _____

_____ Lic. No.: _____ Exp. Date: _____

Telephone Number: _____ Hours of Operation: _____

§ #	REGULATION	COMPLIANCE DETERMINATION	DOCUMENTATION
	<u>PRACTITIONER FACILITY</u>	<u>Yes</u> <u>No</u>	
54.1-3314	Required licenses displayed?	_____	_____
3.3	<u>PHYSICAL STANDARDS FOR FACILITY</u>		
3.3(1)	Area designated as controlled substance serving and storage area?	_____	_____
3.3(3)	Controlled substance for sale maintained separately from other controlled substance maintained for other purposes?	_____	_____
3.3(4)	Work counter space clean and sanitary?	_____	_____
3.3(5)	Counter work space used only for preparation and selling and necessary record keeping?	_____	_____
3.3(7)	Sink with hot and cold running water?	_____	_____
3.3(8)	Facility maintain temperature per specifications for controlled substances?	_____	_____
	<u>ACCESS TO SELLING AREAS</u>		
3.4	Access to stockroom, restroom, and other areas separate from selling area?	_____	_____
3.5	<u>MINIMUM EQUIPMENT</u>		
3.5(1)	Current copy of U.S.P. Dispensing Information?	_____	_____

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		Yes	No	
3.5(2)	Refrigeration with monitoring thermometer maintained in selling area?	_____	_____	
3.5(3)	Current copy of Drug Control Act and Board regulations?	_____	_____	
3.5(4)	Current copy of Virginia Voluntary Formulary?	_____	_____	
3.5(5)	Laminar flow hood, if engaged, in sterile products?	_____	_____	
3.5(6)	Prescription balance and weights?	_____	_____	
3.6	<u>SAFEGUARDS AGAINST DIVERSION OF CONTROLLED SUBSTANCES</u>			
3.6(1)	Sound, microwave, photoelectric, ultrasonic or other generally accepted alarm device installed in the controlled substance selling and storage area?	_____	_____	
3.6(2)	Device maintained in operating order?	_____	_____	
3.6(3)	Device fully protect the immediate controlled substances selling and storage area?	_____	_____	
3.6(4)	Device have auxiliary power source?	_____	_____	
3.6(5)	Device capable of being activated and operated separately from other devices?	_____	_____	
3.6(6)	Alarm system controlled only by the licensee?	_____	_____	
3.7	<u>SELLING AREA ENCLOSURES</u>			
3.7(A)(1)	Enclosure protect the controlled substance stock from unauthorized entry?	_____	_____	
3.7(A)(2)	Enclosure of sufficient height to prevent reaching and gaining access to controlled substances?	_____	_____	
3.7(A)(3)	Entrance to enclosed area have a door which extends from floor and is as high as adjacent counters?	_____	_____	
3.7(A)(4)	Door have adequate locking devices?	_____	_____	
3.7(B)(1)	Licensee in possession of any key to locking device on door of enclosure?	_____	_____	

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		<u>Yes</u> <u>No</u>	
3.7(B)(2)	Emergency key maintained in sealed envelope, signed by licensee and placed in safe or other secured area?	_____	_____
3.8	<u>CONTROLLED SUBSTANCES OUTSIDE OF SELLING AREA</u> Schedule II through VI controlled substances stored outside of selling area secured and access restricted to licensee?	_____	_____
3.9	<u>PRESCRIPTIONS AWAITING DELIVERY?</u> Prescriptions waiting for pick-up stored in a secure place outside selling area?	_____	_____
3.10	<u>EXPIRED CONTROLLED SUBSTANCE SECURITY</u> Separated from stock used for selling and maintained in a designated area with unexpired controlled substances?	_____	_____
4.1	<u>SIGNS AND WRITTEN PRESCRIPTION REQUIREMENT</u> a. Sign posted in public area advising controlled substances may be purchased from a pharmacy? b. Written prescription signed by patient, marked void, and filed chronologically.	_____	_____
4.2 54.1-3404 4.2(A)(1)	<u>MANNER OF MAINTAINING RECORDS FOR PRESCRIPTIONS AND INVENTORY</u> Required inventory of Schedule II through V controlled substances on site and current? a. Biennial inventory (1) Inventory date: _____ (2) Opening of business: _____ (3) Close of business: _____ Inventories and records of Schedule II controlled substances maintained separate from all other records?	_____ _____ _____	_____ _____ _____

§ #	REGULATION	COMPLIANCE DETERMINATION		DOCUMENTATION
		Yes	No	
4.2(A)(2)	Inventories and records of Schedule III through V maintained separately or with records of Schedule VI drugs.	_____	_____	
4.2(A)(3)	Schedule II through V controlled substances records maintained at location as stock of controlled substances to which records pertain for 2 years?	_____	_____	
54.1-3404	Receipt of Schedule II through V controlled substances dated with actual of receipt?	_____	_____	
4.4(B)	<u>RECORDS OF SELLING</u>			
4.4(A)(1)	Records of selling Schedule II controlled substances maintained separate from other records?	_____	_____	
4.4(A)(2)	Schedule II through V selling records include:			
	1. Chronological?	_____	_____	
	2. Selling date?	_____	_____	
	3. Number identifying the sale?	_____	_____	
	4. Patient name and address?	_____	_____	
	5. Name and strength of controlled substances?	_____	_____	
	6. Quantity sold?	_____	_____	
4.4(B)(2)	Records for selling Schedule III - V controlled substances maintained separate or identified with a red 'c' and maintained with Scheduled VI selling record?	_____	_____	
4.3	<u>AUTOMATED DATA PROCESSING RECORDS OF SALE</u>			
4.3(A)(1)	System provides retrieval of selling information for two years in chronological order as required by manual method?	_____	_____	
4.3(A)(2)	Daily print-out of selling records, bound log book, or separate file verified, dated, and signed by licensee?	_____	_____	

§ #	REGULATION	COMPLIANCE DETERMINATION		DOCUMENTATION
5.1	<u>REPACKING OF CONTROLLED SUBSTANCES - RECORDS REQUIRED</u>	<u>Yes</u>	<u>No</u>	
5.1(A)	Control records maintained one year or until expiration date of drug?	_____	_____	
	Record contains:			
	1. Name of drug(s) repackaged?	_____	_____	
	2. Strength of drug?	_____	_____	
	3. Quantity of drug repackaged?	_____	_____	
	4. Initials of supervising licensee?	_____	_____	
	5. Manufacturer or distributors name?	_____	_____	
	6. Control or assigned number?	_____	_____	
	7. Expiration date?	_____	_____	
5.1(B)	Repackaged controlled substance labeled as follows:			
	1. Name and strength of controlled substance?	_____	_____	
	2. Manufacturer's or distributor's name?	_____	_____	
	3. Control or assigned number?	_____	_____	
	4. Proper expiration date?	_____	_____	
5.2	<u>LABELING OF PRESCRIPTIONS AS TO CONTENT AND QUANTITY</u>			
5.2(A)	Label contains the following:			
	1. Name and address of licensee?	_____	_____	
	2. Name of patient?	_____	_____	
	3. Date of selling?	_____	_____	
	4. Controlled substance name and strength	_____	_____	
	5. Number of dosage units or millimeter dispensed?	_____	_____	
5.4	<u>SPECIAL PACKAGING</u>			
5.4(A)	Controlled substances sold in special packaging?	_____	_____	
5.4(B)	Sign posted advising non-special packaging may be requested?	_____	_____	

General Remarks:

Action Taken:

- | | | | |
|-----------|--------------------|-----------|--------------------------|
| (1) _____ | New Inspection | (4) _____ | Drug Destruction |
| (2) _____ | Routine Inspection | (5) _____ | Drug Audit |
| (3) _____ | Reinspection | (6) _____ | Other _____
(Specify) |

Acknowledgement:

This licensee has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions that have been deemed by the inspector as not being in compliance have been explained to me and that I have received a copy of this inspection report.

Inspector (Dept. of Health Professions)

Licensee

Date

Time of Exit

Title of Authorized Individual

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FOR OFFICE USE ONLY

Violations This Inspection: _____

Violations Previous Inspection: _____

Repeated Violations: _____